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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/053,872	04/01/1998	ERIC ROSE	50634BJPWJML	1828

7590 07/18/2002  
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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/18/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/053,872

**Applicant(s)**

ROSE ET AL.

**Examiner**

Jeffrey E. Russel

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-57 is/are pending in the application.
- 4a) Of the above claim(s) 23-37, 40, 41, 43-45 and 47-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38, 39, 42 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 10 May 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:                                          |

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1. Applicants' amendment instructions contained in the response filed Ma 10, 2002 contained numerous inaccuracies. In particular, the first amendment to the specification requested the replacement of the paragraph at page 13, lines 17-35, and at page 14, lines 1-12. However, the paragraph which is to be amended begins at page 13, line 16, and ends at page 14, line 4. In the marked-up copy of this amended paragraph, line 8, "producing" was changed to "prodicing" and at line 11, "IS" was changed to "is" and "3'=TA" was changed to "3'-TA" without the changes being shown in the marked-up copy. The clean copy of this amended paragraph does not correspond to the marked-up copy of the amended paragraph, in that the variables "Xxx", "XXX", "Yyy", "YYY", "Zzz", and "ZZZ" which appear in the marked-up copy were changed to "Nnn" and "NNN" in the clean copy of the amended paragraph. At page 4 of the response filed May 10, 2002, under the heading "In the claims", the response indicates that claims 42 and 46 are to be amended. However, only claims 38, 39, and 42 are actually amended in the response. The marked-up copy of amended claim 38 contains an unmatched beginning bracket at line 5, and numerous words present in claim 38 as originally submitted on February 9, 1999 are missing from the marked-up copy of the amended claim. Claim 42 as originally submitted on February 9, 1999 was not accurately copied in the marked-up copy of amended claim 42 [see, e.g., line 7 ("aglutamyl"), line 12 ("christmas"), and line 14 ("y-carbonyl")]. Any future amendments filed in this application should be carefully checked to ensure full compliance with the amendment rules. Any amendments submitted after final rejection which contain amendment errors such as the ones outlined above will not be entered.

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2. Claims 23-37 and 52-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 40, 41, 43-45, and 47-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. It is noted that Applicants did not list all claims which are readable on the elected species as required in the election of species requirement.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 23-37, 40, 41, 43-45, and 47-57 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

See the attached Raw Sequence Listing Error Report.

In addition, the definition of w in the feature section of SEQ ID NO:1 does not correspond to the definition set forth in the specification. With respect to SEQ ID NO:3, the sequence listing shows terminal w and v residues, although these residues are absent from the sequence as set forth in the specification as originally filed and as amended in the response filed

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May 10, 2002. Also, the definition of w in the feature section of SEQ ID NO:3 does not correspond to the definition set forth in the specification.

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

4. The disclosure is objected to because of the following informalities: In the amendment to the paragraph at page 13, line 16 - page 14, line 4, of the specification, line 8 of the amendment, "producing" is misspelled. Appropriate correction is required.

5. Claim 46 is objected to because of the following informalities: At claim 46, line 4, "Ixa" should be changed to "IXa". Appropriate correction is required.

6. Claim 46 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The factor IXa compounds recited in instant claim 46 are not species of the recombinant muteins required by claim 40, upon which claim 46 depends.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 38, 39, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by the Benedict et al article (J. Clin. Invest., Vol. 88, pages 1760-1765). The Benedict et al article teaches an aqueous saline solution comprising bovine Factor IXa inactivated with Glu-Gly-Arg-

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chloromethylketone. The composition is used as a thrombosis inhibitor. See, e.g., the Abstract; page 1760, column 2, first full paragraph; and Table 1.

9. Claims 38, 39, and 46 are rejected under 35 U.S.C. 102(a) as being anticipated by the Wong et al abstract (Suppl. I Circ., Vol. 92, page I-686). The Wong et al abstract teaches a bolus form of dansyl Glu-Gly-Arg chloromethyl ketone-inactivated bovine Factor IXa.

10. Claims 38, 39, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by the Bajaj et al article. The Bajaj et al article teaches an aqueous composition comprising human Factor IXa inactivated with dansyl Glu-Gly-Arg-chloromethyl ketone. See, e.g., page 153, column 1, first full paragraph. Note with respect to the term “pharmaceutical”, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by the prior art, and the Bajaj et al article teaches every component required to be present by Applicants’ claims.

11. Claims 38, 39, 42, and 46 are rejected under 35 U.S.C. 102(a) as being anticipated by the Lenting et al article. The Lenting et al article teaches an aqueous composition in which human Factor IXa $\beta$ , i.e. Factor IXa, is reacted with Glu-Gly-Arg-chloromethyl ketone. See, e.g., page 14884, column 2, second paragraph; page 14885, column 1, last paragraph; and Figure 2. Note with respect to the term “pharmaceutical”, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by the prior art, and the Lenting et al article teaches every component required to be present by Applicants’ claims.

12. Applicant's arguments filed May 10, 2002 have been fully considered but they are not persuasive.

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The rejection of claims 38, 39, and 46 over the Benedict et al article is maintained.

Applicants contend that the Benedict et al article teaches a bovine rather than a human factor IXa. However, the rejected claims are not limited to human factor IXa, but rather embrace chemically modified bovine factor IXa as well. Patentability must be based upon claimed, not unclaimed, differences over the prior art. For analogous reasons, the rejection of claims 38, 39, and 46 over the Wong et al abstract is also maintained.

The rejection of claims 38, 39, and 46 over the Bajaj et al article is maintained. Chemical modification with a dansyl-containing reagent is permitted and embraced by the rejected claims. The water present in the aqueous solutions of the Bajaj et al article is a pharmaceutically acceptable carrier.

The rejection of the elected claims over the Lenting et al article is maintained. As indicated by the examiner's citation to page 14884, column 2, second paragraph, Factor IXa $\beta$  and Factor IXa are the same - Factor IXa $\beta$  is the fully activated form of Factor IX. Applicants cite to page 14885, first column (this is an incorrect citation - Applicants' quotes are found in the second column), of the Lenting et al article in order to show that the Lenting et al distinguishes between Factor IXa $\beta$  and Factor IXa. However, Applicants misquote the Lenting et al article. In the sections of the Lenting et al article cited by Applicants, the Lenting et al article recites FXIa, not FIXa. Note also that the Lenting et al article is not limited to using the dansylated form of Glu-Gly-Arg-chloromethyl ketone - see, e.g., the Abstract; lines 2-3 of the abbreviations at page 14884, column 2, footnote 1; and Figure 2.

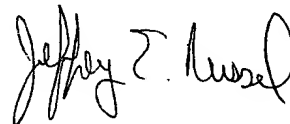
13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel  
7/16/02